REMARKS

The undersigned thanks the Examiner for the courtesies extended during the interview of June 5, 2007. The amendment of claim 22 is fully supported throughout the specification, for example, see page 4, lines 3 and 4, from the bottom of the page. The amendments in the specification have been suggested by the Examiner during the interview and do not introduce new matter as the changes simply provide further clarifications in the examples that were reduced to practice by the inventors.

Specification

The specification was objected for several informalities. A substitute specification is attached herewith correcting the informalities objected to by the Examiner.

Claim Objections

Claims 22, 28-32, 34, and 44-47 were objected for reciting "mycobacterium w" instead of "Mycobacterium w." Appropriate corrections have been made in these claims.

Claim Rejection - 35 U.S.C. §112

Claims 22-47 were rejected under 35 USC 112, first paragraph, for allegedly lack of enabling disclosure. This rejection is respectfully traversed in light of the amendment to the specification as proposed by the Examiner.

The Examiner's position is stated on page 6, last paragraph of the Action as follows:

> The instant specification in its present form, while reciting various preparations of Mycobacterium w, does not specify which of the types was actually utilized nor how much of the composition was administered. The required information to support the instants claims, at a minimum, would be *actual composition administered to the patients* (whole cells, disrupted cells, cell fractions, etc), *the dosage*

administered, the route of administration, and the frequency of administration." [Emphasis added.]

Applicants respectfully submit that persons skilled in the art would recognize by carefully reading the specification that the specification provides enabling disclosure by providing *all* required information to support the instants claims.

Actual composition administered to the patients

Mycobacterium w is a single cell organism. Example 1 discloses "[t]he pharmaceutical compositions" with each dose being 0.1 ml of therapeutic agent. Example 1 contains pharmaceutical compositions A to J. Compositions A, B, C and J contain heat killed whole cell Mycobacterium w. Composition D contains extract of Mycobacterium w after sonication, i.e., after cell disruption. Compositions E to I contain cell fraction extracted Mycobacterium w.

Example 6 teaches the effect of pharmaceutical compositions and method of use. This example states that "[a]t the end of three months patients were administered mycobacterium w containing pharmaceutical compositions. It was administered as 0.1 ml at the interval of one week." This example explains the types of the preparations of Mycobacterium w actually utilized where "mycobacterium w containing pharmaceutical compositions" referring to the "pharmaceutical compositions" of Example 1. Thus, in response to the Examiner's inquiry as to "which of the types [of various preparations of Mycobacterium w] was actually utilized," the answer is that *all* of the types shown as A to J in Example 1 were actually utilized and administered to the patients. Thus, the specification states the actual pharmaceutical compositions administered to the patients.

The dosage administered

In response to the Examiner's inquiry as to "how much of the composition was administered," the answer is that the Mycobacterium w containing pharmaceutical compositions were "administered as 0.1 ml at the interval of one week." See Example 6 of the specification.

The route of administration

Example 4 states that the patient "was given Mycobacterium w interdermally at the interval of one week." In short, the specification teaches a route of administration was interdermal.

The frequency of administration

Both Examples 4 and 6 state that pharmaceutical compositions containing Mycobacterium w was administered "at the interview of one week."

In short, all of the required information to support the instants claims that the Examiner has stated are necessary to support the instant claims were present in the original specification. However, for clarification, Applicants have amended the specification as suggested by the Examiner.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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